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# The International Comparative Legal Guide to:
# Product Liability 2011

## A practical cross-border insight into product liability work

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## Country Question and Answer Chapters:



# EDITORIAL

Welcome to the ninth edition of *The International Comparative Legal Guide to: Product Liability*.

This guide provides the international practitioner and in-house counsel with a comprehensive worldwide legal analysis of the laws and regulations of product liability.

It is divided into two main sections:

15 general chapters. These are designed to provide readers with a comprehensive overview of key product liability issues, particularly from the perspective of a multi-jurisdictional transaction.

Country question and answer chapters. These provide a broad overview of common issues in product liability laws and regulations in 31 jurisdictions.

All chapters are written by leading product liability lawyers and industry specialists and we are extremely grateful for their excellent contributions.

Special thanks are reserved for the contributing editors, Ian Dodds-Smith of Arnold & Porter (UK) LLP and Michael Spencer QC of Crown Office Chambers, for all their assistance.

Global Legal Group hopes that you find this guide practical and interesting.

The International Comparative Legal Guide series is also available online at www.iclg.co.uk

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# Generic Pharmaceutical Liability - Challenges and Changes

Jones, Walker, Waechter, Poitevent, Carrère & Denègre L.L.P.

Steven F. Casey

Generic pharmaceutical manufacturers are waiting anxiously to see how the U. S. Supreme Court treats them in two upcoming cases which have presented the question of federal preemption of state law product liability claims squarely in the court's lap. The court's decision in these consolidated cases will have a significant impact on how product liability lawyers defend their generic drug clients going forward.

## Preemption of State Law Failure to Warn Claims

### Notable decision in the offing

No serious treatment of the state of the law as it relates to generic pharmaceutical manufacturers would be complete without reference to the *Demahy* and *Mensing* cases and the upcoming U. S. Supreme Court consideration of them.

The issue presented in these two important cases is whether state law failure to warn claims against generic pharmaceutical manufacturers are preempted by federal law. In *Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010), and *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009), the United States Courts of Appeal for the 5th and 8th Circuits, respectively, held that federal law did not preempt state law claims. The United States Supreme Court has granted petitions for writs of *certiorari* in both cases and has scheduled oral argument for March 30, 2011. A formal opinion from the court is expected to follow a few months thereafter.

No matter how the U. S. Supreme Court decides these two cases, the decision will have a significant impact on the generic pharmaceutical industry and product liability litigation concerning it.

### *Demahy*

In *Demahy*, the plaintiff's physician prescribed the drug Reglan to treat gastroesophageal reflux. The plaintiff's pharmacist filled the prescription with the generic form of the drug, called metoclopramide, that had been manufactured by Actavis. Although it is well known that prolonged use of the drug is associated with a movement disorder, tardive dyskinesia, Ms. Demahy took metoclopramide for four years. She developed symptoms of tardive dyskinesia and sued Actavis alleging that the manufacturer failed to adequately warn of the risks of the drug.

Actavis argued that Demahy's state law claims of failure to warn was preempted by federal law.

The court notes early in the *Demahy* opinion that the risks of tardive dyskinesia were required by the FDA to be disclosed in metoclopramide labeling since 1985. It also mentions a February 2009 labeling revision—widely known in the industry as a "black box" warning—that speaks to the dangers of prolonged use of the drug, but omits the fact that the black box language added very little of substance.

In 1984, the Food, Drug and Cosmetic Act was amended by the so-called Hatch-Waxman Amendment to allow for the post-patent manufacture of established drugs by new manufacturers who only had to establish a few limited items in order to have an Abbreviated New Drug Application (ANDA) approved by the Food and Drug Administration (FDA). The policy behind allowing such generic forms of previously approved drugs to be manufactured was to allow lower cost drugs to come to market in the United States. Essentially, once an innovator drug's patent expired, a generic manufacturer could obtain approval from the FDA to manufacture and sell the drug by demonstrating that its drug was bioequivalent and that the labeling proposed by the new manufacturer was the same as the label used by the brand name manufacturer. In fact, the generic manufacturer, in its ANDA, was obliged to include a side-by-side comparison of the two labels to demonstrate that its label was the same as the old label.

In contrast, a manufacturer which develops, or innovates, a new drug must demonstrate, through a rigid and lengthy process, including scientific studies it and perhaps others have conducted, that the drug is both safe and effective. A generic drug only comes to the market years after an innovator company has made such a demonstration, during which time the drug has been on the market and many, many doses of it have been administered, resulting in significant experience as to its safety and efficacy even after approval by the FDA.

The reasoning behind the generic drug industry concept is that any further costly research regarding the safety and efficacy of a drug that had been approved by FDA years earlier was unnecessary and duplicative. Theoretically, a drug coming off patent has been on the market long enough so that its relative safety for use has been effectively established. The idea, of course, was that without the cost of the studies performed by the original innovator, or brand manufacturer, the generic manufacturers could see the drug to the market at much lower costs to consumers.

Plaintiff theories of liability against generic drug manufacturers invariably include failure to warn claims, asserting that there is scientific evidence available that requires the manufacturer to provide further, or more stringent, warnings about its use or possible side effects. Generic manufacturers typically respond by pointing out the clear requirement, imposed by the FDA, that in order to get approval to market a drug, a generic company must

demonstrate that its label is the same as that of the brand manufacturer of that drug. The logical extension of that argument has been that, if generics do comply with that rule, then they should be free from attack over the label; in other words, that the federal requirements regarding labeling preempt state law failure to warn claims.

In the *Demahy* case, Judge Patrick Higginbotham, a Bessemer, Alabama native, wrote for the 5th Circuit that there was insufficient statutory evidence to conclude that Congress intended to provide preemption protection to *generic* manufacturers. In so holding, the 5th Circuit followed what it considered to be the foreshadowing decision of the U. S. Supreme Court in *Wyeth v. Levine*, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009). In *Levine*, the U. S. Supreme Court held that FDA labeling requirements did not preempt state law claims against *brand name* manufacturers.

In analysing the statutory and regulatory framework that controls the generic industry, the *Demahy* court first found that the FDA regulation that requires a generic drug's label to be "the same as" its brand name counterpart only applies to the *initial* labeling described in the manufacturer's ANDA. It reached this conclusion because the regulations are "silent as to the manufacturer's obligations after the ANDA is granted", *Demahy* at 20, citing *Bartlett v. Mutual Pharm. Co*, 659 F. Supp. 279 (D. N. H. 2009), 2009 U. S. Dist. LEXIS 90528, 2009 WL 3126305, at *12 (quoting *Stacel*, 620 F. Supp. 2d at 907). In reaching this conclusion, the court ignored the fact that the FDA has routinely taken the position that a generic's label must *always* be the same as that of the brand. This has been the FDA's practice, even though it has withdrawn an amicus brief saying so which it had filed in another significant preemption case. This backtracking of the FDA on this official position was notable to the *Demahy* court.

After concluding that there is nothing in the FDA regulations saying that generics don't have an obligation to update their label, *Demahy* lists several methods available to brand name drug manufacturers to make changes in labeling, and eventually indicates that these same methods are available to generic manufacturers as well.

The first way labeling changes might be made, according the court, is the use of a "changes being effected" (CBE) mode of operation. This allows a manufacturer to go ahead and change its label—while asking the FDA to approve that change—before the FDA gives final approval for such.

The court also referenced the "prior approval" method, whereby a manufacturer requests permission for a labeling change before making the change, and waits for approval from FDA before implementing it.

The court also mentioned the use of so-called "Dear Doctor" letters as another method of changing instructions for use or warnings in a drug's labeling.

In FDA regulations for each of those 3 methods, there is no specific language applying them to generics. The *Demahy* court stated, in no uncertain terms, that if Congress had wanted these methods of changing warnings not to apply to generics, it could have said so. The converse argument seems just as strong of course—if Congress had wanted these methods to apply to generics, Congress could've specifically pointed that out as well. One could almost flip a coin to determine what side of that argument one adheres to.

Regardless of the fact that the generic manufacturing industry and the FDA had hammered out a fairly standard practice of dealing with labeling issues—even if those standard practices weren't always entirely consistent with the wording found in the statutes and regulations—Demahy affirmed the basic premise that a drug manufacturer remains primarily responsible for maintaining its labeling consistent with principles of safety and efficacy in the use of its products.

## *Mensing*

In *Mensing*, the United States Court of Appeals for the Eighth Circuit reached the same conclusion that was reached in *Demahy*, and stated that "[f]ar from prohibiting [generic drug manufacturers] from taking steps to warn their customers of new safety hazards, federal law requires such action". *Id*. at 614.

Interestingly, Ms. Mensing had taken the same drug—metoclopramide—as had Ms. Demahy, and she took it for the same length of time—4 years—even though the label indicated that it was only intended for short duration use, defined in the label as no longer than 12 weeks. The plaintiff's physician had prescribed the drug for another of its approved uses—the treatment of diabetic gastroparesis. As in *Demahy*, the plaintiff in Mensing developed tardive dyskinesia, and filed a suit against the manufacturers of the generic metoclopramide that she took, claiming that they had failed to adequately warn her of the risks of that particular side effect. Additionally, Mensing asserted that the defendants "promoted metoclopramide for long term use even though the FDA had approved the drug only for use up to 12 weeks". *Id.* at 606.

The *Mensing* court recited the same essential arguments made by both plaintiff and defendants as did *Demahy*, but the *Mensing* court dismissed the CBE issue out of hand, saying that even if the CBE rules were not available to generics, the prior approval method of effecting needed labeling changes was. *Mensing* noted, as did *Demahy*, a legal presumption against preemption.

*Mensing* rejected the defendants' argument in favour of preemption, and found that "[t]he regulatory framework makes clear that a generic manufacturer must take steps to warn its customers when it learns it may be marketing an unsafe drug". *Mensing*, at 608. In fact, in response to the defendants' argument that generics are limited in how they are able to effect labeling changes under the FDA regulations, the court stated bluntly: "[t]he generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product". *Id*. at 611.

Although perhaps not particularly important, a difference in *Demahy* and *Mensing* exists on the issue of whether a generic drug label must be "the same as" that of the brand name drug only at the application process or during the lifetime of the drug. *Demahy* repeatedly points out that the regulations only speak to the ANDA process, while *Mensing* recognises that "[t]he parties agree that generic labels must be substantively identical to the name brand label even after they enter the market". *Mensing*, at 608.

Nonetheless, *Demahy* and *Mensing* both concluded that state law claims against generic drug manufacturers are not preempted by federal law. Each opinion relied in part on the U. S. Supreme Court's ruling in *Wyeth v. Levine*, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009), which reached the same conclusion—rejecting preemption—in cases involving brand name drug manufacturers.

## *Levine*

As stated hereinabove, the U. S. Supreme Court, in *Wyeth v. Levine*, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009), found that federal law did not preempt state law failure to warn claims against brand name drug manufacturers. In *Levine*, the plaintiff was a professional musician who had to have an arm amputated as a result of the infiltration into arterial blood of an attempted intravenous use of the drug Phenergan. Even though the danger of such damage caused by the drug if it reached an artery was well known, and stated in the drug's labeling, the court found that it was appropriate for a state court jury to determine if the warning was adequately stated and conveyed.

*Levine* contains a thorough review of the types of preemption available in the law and rejects the application of each one in its context.

The *Levine* ruling represents a 6-3 decision by the court, which includes an opinion by Justice Clarence Thomas, concurring in the result but for different reasons.

## Prediction

While it is impossible to forecast with any guarantee of accuracy what the U. S. Supreme Court will do in any given case, it does no harm, either, especially if one provides some thought as to the decision's effect no matter what the result. I will attempt to do so here.

Assuming the justices line up the same for *Demahy* and *Mensing* as they did in Levine, one would predict a decision in the plaintiffs' favour; however, it has been reported that Justice Elena Kagan has recused herself from this proceedings, which would make the margin a closer 5-3. Justice Thomas's opinion demonstrates a lack of enthusiasm for federal preemption, which suggests that he would lean towards the plaintiffs' argument in the upcoming argument, even if the issues are thought to be different since generics are involved rather than the brand. Even if Justice Thomas sided with the *Levine* minority, then, the vote would be 4-4, and would result in favour of the lower court's ruling. Here, that would mean that the conclusions of the Fifth and Eighth Circuits--that there is no federal preemption in favour of generic drug manufacturers in state law failure to warn claims--prevail.

Although the odds do not seem to heavily favour one side or the other, it is my thought that the scales will tip slightly in favour of the plaintiffs, so that the decisions of the two lower appellate courts here are affirmed.

## Ramifications

**If the plaintiffs win**—If *Demahy* and *Mensing* are affirmed, it will be back to "business as usual" for the world of failure to warn litigation involving generic drug manufacturers in the U.S. All of the cases that have been stayed pending the outcome of these two cases will be re-opened, discovery will continue and the cases set for trial.

What *will* change, however, in the event of a plaintiff win, is how generic drug manufacturers do business. Regardless of what the appellate courts think, the costs of generic drugs to the consumer will be increased. In order to shoulder the labeling burden placed on them by such a decision, generic companies will be compelled to increase spending and the devotion of manpower to monitoring the scientific literature, to evaluating adverse event reports for the development of trends and to making crucial decisions as to whether to changes labeling information or suggest such changes to FDA. Their employees will also need to learn how to use the FDA's CBE rules—something generics have not thought were applicable to them. For each of these issues that will demand attention from management, decisions will have to be made as to whether to try to place these new responsibilities on current staff, or hire new personnel or even contract such duties to outside groups. While the courts in *Demahy* and *Mensing* don't seem to think this increased effort will result in much increased cost, that thinking reflects a misunderstanding of the generic industry and even a bit of *naivete* on the jurists' part.

On the litigation front, a plaintiff win in these cases will force generics who find themselves in failure to warn cases to emphasise their defence on at least two fronts:

1. Generics will need to defend their labels. The content and format of each one will be fair game for the plaintiff counsel to attack, and the defendant manufacturer will still need to be able to show that it complied with FDA requirements. The manufacturer will still need to demonstrate that the label was "the same as" that of the brand manufacturer and, while this will not constitute a complete defence, it should still be admissible as evidence of the standard of care and adequacy of the warning.
2. Generics must also combat, if appropriate, any new information that the plaintiff counsel and plaintiff experts say should be included in the label:
   (i) Is there any scientific basis for the new information? Often, such evidence amounts to speculative science without any real support in the scientific community.
   (ii) Is the additional information the plaintiff proposes logical to include? Plaintiff experts will often misinterpret data from scientific studies and compare different types of studies to yield illogical epidemiological results (e.g., comparison of prevalence studies to incidence studies).
   (iii) Hasn't the FDA known of the proposed new information for some time and not decided to include it in the label? Just because the defence of preemption might no longer be available, that doesn't mean that it's not still the FDA's responsibility to assess data provided to it and change a drug's label if appropriate.

**If the defendants win**—If *Demahy* and *Mensing* are reversed, and the U. S. Supreme Court finds that federal law preempts state law failure to warn claims against generic drug manufacturers, then the initial thought will be that all similar cases that are pending around the country will be decided in the defendants' favour. This depends, of course, on whether the decision is deemed to be retroactive. If it is then summary judgments in pending cases will largely be granted, and the plaintiff counsel in each one will be scrambling to find alternative theories of liability for their clients. If the decision is not retroactive, then trial courts will be faced with questions as to how to apply the new decision to the pending cases.

Further, if the court finds that there is preemption, but in its opinion makes statements that affect the generic manufacturers' obligations for pharmacovigilance, for example, then generics will have to decide how to respond, both in court and in the operation of their businesses. Of course, such comments might be considered mere *dicta*, but even *dicta* from the U. S. Supreme Court often has wide-ranging impact. From such remarks might spring new theories of liability for plaintiffs or areas of exposure for generic drug defendants.

Additionally, regardless of which side prevails, there may be efforts made to resolve the remaining issues legislatively. Much of the court's reasoning related to the obligations of generic manufacturers with respect to their labels rests on the court's view of legislative intent, and Congress could certainly act to correct any perceived misreading by the court.

From a litigation standpoint, if the generics prevail in the U. S. Supreme Court, then trial courts where such cases are pending will be flooded with motions for summary judgment based on preemption. At that point, battle lines will form around issues such as retroactivity, mentioned above, and whether there are other, valid claims for relief that the plaintiffs might have pled. Trial courts will likely allow ample time for the plaintiff counsel to amend complaints to assert any new claims that are designed to skirt the preemption issue and, in that event, we can expect to see claims ranging from straight negligence to intentional acts asserted in an effort to keep plaintiffs' claims alive.

## Further Prediction Based on *Conte*

Particularly if the defendant manufacturers prevail in *Demahy* and *Mensing*, we are likely to see an effort by plaintiffs to revisit the arguments accepted by the California Court of Appeals in *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299 (2008). *Conte* is the only appellate court known to have found that a brand name drug manufacturer has a duty to adequately warn those taking generic drugs because of the fact that the brand's labeling is the one read and relied upon by the consumer or her doctor.

If the U. S. Supreme Court recognises preemption in state law tort claims against generic manufacturers, look for the plaintiff counsel to begin to push the *Conte* argument again. Despite the fact that many courts have rejected this argument thus far, it may see a resurgence if the alternative is to leave injured plaintiffs without a remedy.

## Conclusion

As shown from the description of the issues presented in the *Demahy* and *Mensing* cases, the U. S. Supreme Court is presented with an interesting set of arguments. The court's decision, expected sometime in the summer of 2011, will have a significant impact on the generic drug industry in the U. S., and could conceivably affect generic drug prices as much as military flare-ups in the Middle East affect oil prices. While the far-reaching impact of this decision cannot be predicted in its entirety, it may be that a legislative fix will be needed to balance out the impact of the court's decision.

## Addendum

On June 23, 2011, the U. S. Supreme Court released its highly anticipated ruling in PLIVA, Inc. v. Mensing, 564 U.S. ___, 180 L. Ed. 2d 580, 2011 U. S. LEXIS 4793 (2011). In a 5-4 opinion, the Court held that state law failure to warn claims against generic drug manufacturers are preempted by state law.

As predicted, this opinion has sparked a flurry of activity in the thousands of affected cases pending around the U. S. Defence lawyers immediately began telephoning their opponents, inquiring as to whether they are willing now to dismiss their claims voluntarily, and are busily drafting summary judgment motions in case plaintiff lawyers refuse. Plaintiff lawyers are busy trying to articulate variant theories of liability and asking trial courts to give them more time to do so. For the most part, trial judges are allowing the parties time to assess their positions, although at least one trial judge has issued a show cause order ex mero motu based on the Mensing opinion. Also, as predicted, there seems to be renewed interest in the liability theory recognised in Conte, supra, where plaintiffs assert fault to the brand name manufacturers for failure to warn even though the drug they took was generic.

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Jones, Walker, Waechter, Poitevent, Carrère & Denègre L.L.P., is a full service law firm of over 300 lawyers, providing a wide range of legal services to a national and international corporate client base through offices in Alabama, Arizona, the District of Columbia, Florida, Louisiana, and Texas. Jones Walker prides itself as the go-to law firm in the Gulf South for highly regulated industry, and the members of the firm's product liability group–the firm's largest litigation practice group--represent domestic and foreign manufacturers, distributors, and end-users, both large and small, in state and federal courts and before administrative agencies. This litigation group is complemented by professionals in healthcare law and regulation and governmental affairs. We are a skilled provider of high-quality, low-cost legal services, and we excel at project management and staffing for optimum cost control. Along with risk management advice, we offer an array of preventive services designed to acquaint clients and key personnel with effective techniques for minimising exposure to product liability-related loss or controlling exposure when a suit has been filed. We counsel clients on compliance with regulations, labeling, warning, and sales and distribution products. We can help clients make decisions regarding record keeping protocols when designing or redesigning products to help minimise exposure to loss.

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